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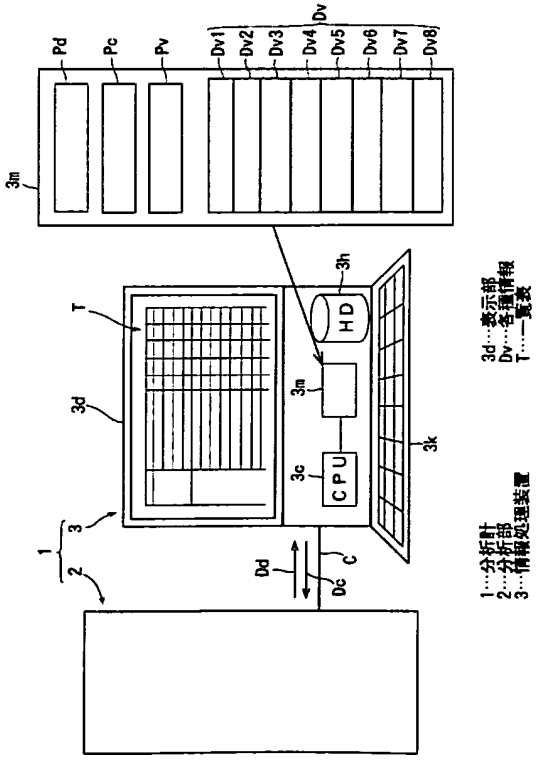
(54)【発明の名称】　分析計の妥当性確認方法、妥当性確認機能を有する分析計および分析計の妥当性確認プログラムを記録した記録媒体

(57)【要約】

【課題】　分析計が適正なものであることの妥当性の確認が、抜けなく、容易かつ確実できる分析計の妥当性確認方法、妥当性確認機能を有する分析計および分析計の妥当性確認プログラムを記録した記録媒体を提供する。

【解決手段】　分析部２と、この分析部２からの分析値を処理する情報処理装置３とを備えた分析計１において、行おうとする分析に関して品質を保証する複数の検査項目$V_0$とその検査結果$V_5$を含む各種情報Ｄｖを、前記分析計１に設けた情報処理装置３で記録し、この情報処理装置３が検査結果$V_5$を変更不能とすると共に、検査項目$V_0$とその検査結果$V_5$を出力することで前記分析計が適正なものであることを証明する。



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【特許請求の範囲】

【請求項１】　分析部と、この分析部からの分析値を処理する情報処理装置とを備えた分析計において、行おうとする分析に関して品質を保証する複数の検査項目とその検査結果を含む各種情報を、前記分析計に設けた情報処理装置で記録し、この情報処理装置が検査結果を変更不能とすると共に、検査項目とその検査結果を出力することで前記分析計が適正なものであることを証明することを特徴とする分析計の妥当性確認方法。

【請求項２】　前記分析計の品質を保証する各種情報として、分析計の製造者が行なう決定分析計型式、出荷試験および据付試験に加えて、分析計の使用者が行なう校正試験、定期検査、日常検査および分析法を記録する請求項１に記載の分析計の妥当性確認方法。

【請求項３】　前記各種情報として、検査方法を示す情報、管理基準を示す情報、検査に用いる標準機器や標準試料を示す情報をそれぞれ記録する請求項１または２に記載の分析計の妥当性確認方法。

【請求項４】　前記情報処理装置が、各種情報を検査項目に分けて一覧表にして表示し、検査者が前記一覧表から行うべき検査項目を選択することにより、該当する検査項目の検査方法を表示し、検査者が表示された方法によって検査を行なった後に、帳票記録の責任者の指示で検査結果を保存する請求項３に記載の分析計の妥当性確認方法。

【請求項５】　前記分析計の使用者が行なう校正試験、定期検査、日常検査および分析法の各検査項目において、使用者が検査方法を示す情報、管理基準を示す情報、検査に用いる標準機器や標準試料を示す情報、および、帳票様式を示す情報を、変更できるようにすると共に、情報の変更履歴を残すようにした請求項３または４に記載の分析計の妥当性確認方法。

【請求項６】　分析部と、この分析部からの分析値を処理する情報処理装置とを備えた分析計において、行おうとする分析に関して品質を保証する複数の検査項目を含む各種情報とその検査結果を変更不能に記録するコンピュータ読み書き可能な記録媒体と、記録された情報の出力により前記分析計が適正なものであることを証明する表示部とを有することを特徴とする妥当性確認機能を有する分析計。

【請求項７】　前記分析計の品質を保証する各種情報が、分析計の製造者が行なう決定分析計型式、出荷試験および据付試験に加えて、分析計の使用者が行なう校正試験、定期検査、日常検査および分析法である請求項６に記載の妥当性確認機能を有する分析計。

【請求項８】　前記各種情報が、検査方法を示す情報、管理基準を示す情報、および、検査に用いる標準機器や標準試料を示す情報をそれぞれ有する請求項６または７に記載の妥当性確認機能を有する分析計。

【請求項９】　前記表示部が、各種情報を検査項目に分

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けて一覧表にして表示し、検査者が前記一覧表から行うべき検査項目を選択することにより、該当する検査項目の検査方法を表示するものであり、検査者がこの表示部に表示された方法によって検査を行なった後に、帳票記録の責任者の指示によって前記情報処理装置が検査結果を保存するように構成した請求項８に記載の妥当性確認機能を有する分析計。

【請求項１０】　前記分析計の使用者が行なう校正試験、定期検査、日常検査および分析法の各検査項目において、検査方法を示す情報、管理基準を示す情報、検査に用いる標準機器や標準試料を示す情報、および、帳票様式を示す情報を、使用者によって変更できると共に、情報の変更履歴を残すように構成した請求項８または９に記載の妥当性確認機能を有する分析計。

【請求項１１】　分析部と、この分析部からの分析値を処理する情報処理装置とを備えた分析計の前記情報処理装置に組み込まれるプログラムであって、行おうとする分析に関して品質を保証する複数の検査項目とその検査結果を含む各種情報を、前記情報処理装置により読み書き可能な記録媒体に記録し、記録された検査結果を変更不能とすると共に、各種情報の出力により前記分析計が適正なものであることを証明可能としたことを特徴とする分析計の妥当性確認プログラムを記録したコンピュータ読み取り可能な記録媒体。

【発明の詳細な説明】

【０００１】

【発明の属する技術分野】本発明は分析計の妥当性確認方法、妥当性確認機能を有する分析計および分析計の妥当性確認プログラムを記録した記録媒体に関するものである。

【０００２】

【従来の技術】従来より、分析計には情報処理装置を組み込む場合があり、このような分析計は、測定対象の各種状態量を分析値として検出する検出器からなる分析部の制御や、この分析部から得られた分析値の処理を情報処理装置（コンピュータ）によって行っていた。すなわち、この情報処理装置で分析部からの分析値の読み込み、演算、伝達等を行うことにより、より有用な分析計を提供することが行われている。

【０００３】また、近年では前記分析計によって測定された分析値の信頼性や分析計の妥当性を保証するために、分析計から得られた測定値の信頼性と、分析法の正当性を確認する妥当性確認を行うことが世界的規模で求められるようになってきている。特に貿易の自由化に伴い、これらの分析計を海外でも使用する場合、各国の法律によって定められた妥当性確認の基準に合わせて分析値および分析計の妥当性を証明する必要が生じることがある。

【０００４】図３は従来の分析計１０における妥当性確認方法を説明する図である。図３において、従来の分析

計１０は、分析部１１と、この分析部１１に接続される情報処理装置１２（コンピュータ）とからなる。また、この分析計１０は、製造時に仕様書やＩＳＯ証明書など、分析計１０の各種決定分析計型式を記載した帳票１３を保管するファイル$F_0$を有しており、例えば各分析計１０の出荷時に行なう出荷試験の内容や、据付試験の内容を記載した帳票１４なども収めた状態で、分析計１０の製造者側で保管されている。

【０００５】一方、分析計１０の使用者側では使用者が行なう校正試験、定期検査、日常検査の内容を記載した帳票１５、１６、１７を保管するファイル$F_1$, $F_2$, $F_3$をそれぞれ保管している。これらのファイル$F_1$, $F_2$, $F_3$にはそれぞれ校正試験、定期検査、日常検査のテスト方法、管理基準および標準機器や標準試料として使用するものなどの詳細を記録したものが収められており、これらを参照しながら分析計１０の管理を行っていた。

【０００６】また、これらに加えて分析法を記録した帳票１８を保管するファイル$F_4$を用意して、分析計１０によって行った各測定の記録を残すようにもしている。したがって、前記分析計１０による分析値が妥当かどうかを、例えば１年に１回確認する場合には、前記ファイル$F_1$～$F_4$を用いて帳票１５～１８を確認すればよい。また、導入された時点での分析計１０の妥当性を確認する場合は、製造者が保管しているファイル$F_0$を確認することができる。

【０００７】

【発明が解決しようとする課題】ところが、上述した方法で管理する場合には、管理基準等の膨大な量の標準書に加えて、分析の妥当性を証明するために、管理基準に基づく管理の実施と適否判断および記録を帳票１３～１８によって行い、これらを確実に保管しておかなければならなかった。したがって、多くの帳票１３～１８を必要とし、これらをファイル$F_0$～$F_4$やノートなどによって保管する必要があるが、使用者の実施忘れや、記録等の抜け、さらには、管理忘れや紛失などが起こる可能性があった。また、分析計１０の出荷前および設置時の段階における検査の記録は製造者側で保存されるものであるから、使用者側で確認することができないという欠点もあった。

【０００８】本発明は、上述の事柄を考慮に入れてなされたものであって、その目的とするところは、分析計が適正なものであることの妥当性の確認が、抜けなく、容易かつ確実できる分析計の妥当性確認方法、妥当性確認機能を有する分析計および分析計の妥当性確認プログラムを記録した記録媒体を提供することにある。

【０００９】

【課題を解決するための手段】上記目的を達成するため、本発明の分析計の妥当性確認方法は、分析部と、この分析部からの分析値を処理する情報処理装置とを備えた分析計において、行おうとする分析に関して品質を保証する複数の検査項目とその検査結果を含む各種情報を、前記分析計に設けた情報処理装置で記録し、この情報処理装置が検査結果を変更不能とすると共に、検査項目とその検査結果を出力することで前記分析計が適正なものであることを証明することを特徴としている。

【００１０】したがって、妥当性確認に必要な各検査項目とその検査結果を含む各種情報を、既存の情報処理装置によって保管するので、分析計の構成を複雑にすることなく確実にデータを保管できる。すなわち、使用者に手間をかけることがないだけでなく、分析計の使用者による管理作業の実施忘れ、記録忘れ、保管忘れ、および、記録用紙の紛失が生じることがなく、確実に妥当性確認を行うことができる。なお本発明において、検査と表現する作業には分析計の校正作業や調整作業も含まれている。

【００１１】また、前記分析計の品質を保証する各種情報として、分析計の製造者が行なう決定分析計型式、出荷試験および据付試験に加えて、分析計の使用者が行なう校正試験、定期検査、日常検査および分析法を記録する場合には、分析計の出荷前や設置時の段階における出荷試験、据付試験および校正試験の結果などの情報も妥当性確認のために参照することができる。すなわち、この分析計を、妥当性確認のための基準が異なるあらゆる地域において使用することができる。

【００１２】さらに、前記各種情報として、検査方法を示す情報、管理基準を示す情報、検査に用いる標準機器や標準試料を示す情報をそれぞれ記録する場合には、分析計の設置時に必要な使用者側の資料として、分析計の検査方法や、管理基準、さらには、分析計の検査に用いる標準機器や標準試料などの各情報を分析計の情報処理装置に入力して保存しているので、従来別途用意されていた管理基準等の膨大な量の標準書を用紙などで保管する必要がなくなる。

【００１３】前記情報処理装置が、各種情報を検査項目に分けて一覧表にして表示し、検査者が前記一覧表から行うべき検査項目を選択することにより、該当する検査項目の検査方法を表示し、検査者が表示された方法によって検査を行なった後に、帳票記録の責任者の指示で検査結果を保存する場合には、必要なときに行なうべき検査方法の指示を極めて容易に得ることができるので、手間を少なくできると共に、誰が検査を行っても同じ条件で検査を行なうことができる。すなわち、分析計の妥当性確認をより確実に行うことができる。なお、本発明において、検査者と表現する者には、分析計の校正作業や調整作業を行なう作業者も含まれる。

【００１４】前記分析計の使用者が行なう校正試験、定期検査、日常検査および分析法の各検査項目において、使用者が検査方法を示す情報、管理基準を示す情報、検査に用いる標準機器や標準試料を示す情報、および、帳票様式を示す情報を、変更できるようにすると共に、情

報の変更履歴を残すようにした場合には、使用者の必要に合わせて校正試験、定期検査、日常検査および分析法の内容を変更可能であるので、自由度が増すと共に、変更履歴が残るので妥当性確認に必要な情報を残すことができる。

【００１５】本発明の妥当性確認機能を有する分析計は、行おうとする分析に関して品質を保証する複数の検査項目を含む各種情報とその検査結果を変更不能に記録するコンピュータ読み書き可能な記録媒体と、記録された情報の出力により前記分析計が適正なものであることを証明する表示部とを有することを特徴としている。すなわち、分析計に取り付けられた情報処理装置で妥当性確認の必要な全てを管理することができ、分析計およびこの分析計による分析の信頼性を保証することができる。

【００１６】前記分析計の品質を保証する各種情報が、分析計の製造者が行なう決定分析計型式、出荷試験および据付試験に加えて、分析計の使用者が行なう校正試験、定期検査、日常検査および分析法であってもよい。

【００１７】また、前記各種情報が、検査方法を示す情報、管理基準を示す情報、および、検査に用いる標準機器や標準試料を示す情報をそれぞれ有するものであってもよい。この場合、前記表示部が、各種情報を検査項目に分けて一覧表にして表示し、検査者が前記一覧表から行うべき検査項目を選択することにより、該当する検査項目の検査方法を表示するものであり、検査者がこの表示部に表示された方法によって検査を行なった後に、帳票記録の責任者の指示によって前記情報処理装置が検査結果を保存するように構成してもよい。

【００１８】さらに、前記分析計の使用者が行なう校正試験、定期検査、日常検査および分析法の各検査項目において、検査方法を示す情報、管理基準を示す情報、検査に用いる標準機器や標準試料を示す情報、および、帳票様式を示す情報を、使用者によって変更できると共に、情報の変更履歴を残すように構成してもよい。

【００１９】本発明の分析計の妥当性確認プログラムを記録した記録媒体は、行おうとする分析に関して品質を保証する複数の検査項目とその検査結果を含む各種情報を、前記情報処理装置により読み書き可能な記録媒体に記録し、記録された検査結果を変更不能とすると共に、各種情報の出力により前記分析計が適正なものであることを証明可能としたことを特徴としている。

【００２０】



【発明の実施の形態】図１は本発明の妥当性確認機能を有する分析計１の一例を示す図である。図１において、２は例えば測定対象試料中に含まれる微量炭素や硫黄の含有量を、燃焼したガスの赤外線ガス分析によって求める分析部、３はこの分析部２に接続される情報処理装置３（以下、コンピュータという）である。コンピュータ３はＣＰＵ３ｃと、メモリ３ｍと、補助記憶装置の一例であるハードディスク３ｈと、表示部の一例であるディスプレイ３ｄと、キーボード３ｋとを有している。なお、本発明は分析計２の種類を限定するものではないことは言うまでもない。

【００２１】前記コンピュータ３は通信ケーブルＣを介して分析部２からの測定値Ｄｄを入力してこれを処理するデータ処理プログラムＰｄと、分析部２を制御する制御コマンドＤｃを出力する制御プログラムＰｃと、前記分析計２が適正なものであることを証明する妥当性確認プログラムＰｖ（以下、バリデーションプログラムという）を実行する。各プログラムＰｄ，Ｐｃ，Ｐｖは何れも例えば、ハードディスク３ｈなどのコンピュータ読み取り可能な記録媒体から読み出してメモリ３ｍに書き込まれた状態で実行される。

【００２２】また、Ｄｖは前記バリデーションプログラムＰｖによって保存されるバリデーションデータである。なお、このバリデーションデータＤｖはメモリ３に保存されるだけでなく、ハードディスク３ｈや不揮発性メモリなどの補助記憶装置に保存されて、その内容が消滅しないようにしている。

【００２３】図２は前記ディスプレイ３ｄに表示される画面の表示例を示すものであり、本例では、行おうとする分析に関して品質を保証する複数の検査項目とその検査結果を示す一覧表Ｔを表示するものである。また、この一覧表Ｔは前記妥当性確認プログラムＰｖによる処理内容を示している。一覧表Ｔが示すように、前記バリデーションデータＤｖは大きく８つに分けられた体系を有している。

【００２４】すなわち、前記バリデーションデータＤｖは使用者側の分析計１に対する要求仕様Ｄｖ１、これに対応して製造者が定めた分析計１の決定分析計型式Ｄｖ２、分析計１を使用者に納入する時点で行う出荷試験Ｄｖ３、据付試験Ｄｖ４、使用者側で行う校正試験Ｄｖ５、定期検査Ｄｖ６、日常検査Ｄｖ７、および、使用者が定める分析方法を示す分析法Ｄｖ８に分類されている。

【００２５】前記各体系のバリデーションデータＤｖ１～Ｄｖ８のそれぞれは、分析計１の種類にしたがって複数の項目が用意されている。例えば、本例の場合、決定分析計型式Ｄｖ２として、ＩＳＯ品質システムの取得証明書、ソフトウェア宣言書などの各種情報項目だけでなく、標準試料並行精度、標準試料直線性、分析元素と分析範囲、感度～振動などの検査項目$V_0$を有している。

【００２６】また、前記バリデーションデータは各検査項目$V_0$に対応して、検査方法を示す情報$V_1$、管理基準を示す情報$V_2$、検査に用いる標準機器や標準試料を示す情報$V_3$、検査結果を開示する帳票の様式を示す情報$V_4$および帳票記録の責任者を特定する情報$V_5$を有している。

【００２７】前記一覧表Ｔに示すように、上述した８体

系のうち、決定分析計型式Ｄｖ２、出荷試験Ｄｖ３、据付試験Ｄｖ４および校正試験Ｄｖ５の各検査項目$V_0$は、その検査方法、管理基準、検査に用いる標準機器や標準試料を示す情報$V_1$，$V_2$，$V_3$の内容は分析計１の出荷時点で製造者によって定められ、これがメモリ３ｍや外部記憶装置３ｈなどに記録（保存）されている。また、上述の各検査項目$V_0$の情報$V_1$，$V_2$，$V_3$の内容が、例えば、製造者側の検査者、すなわち品質システム管理者Ｓｍによって保存されるものであることを、一覧表Ｔの中に”Ｓｍ”と表記することによって表わしている。（以下の各項目においても同様）

【００２８】なお、上述の各検査項目$V_0$における帳票様式を示す情報$V_4$の記録は製造者側の機器検査者Ｉｍによって行われる。また、前記検査項目$V_0$の検査結果を示す情報$V_5$の記録は、帳票記録の責任者、すなわち、製造者側の全責任者Ａｍまたは製造者側の機器検査者Ｉｍによって行われる。

【００２９】一方、要求仕様Ｄｖ１、校正試験Ｄｖ５、定期検査Ｄｖ６、日常検査Ｄｖ７、分析法Ｄｖ８の各検査項目$V_0$の情報$V_1$，$V_2$，$V_3$の内容は、分析計１の使用者側の検査者、すなわちシステム管理者Ｓｕおよび作業者Ｏｕによって定められてこれが保存される。また、各検査項目$V_0$の検査結果を示す情報$V_5$の記録は、使用者側の帳票記録の責任者である全責任者Ａｕの指示によって行われる。

【００３０】なお、上述の一覧表Ｔに示した例において、校正試験Ｄｖ５の各検査項目$V_0$の情報$V_1$～$V_4$の内容は出荷時に予め分析計１の製造者側の品質システム管理者Ｓｍおよび機器検査者Ｉｍによって定められているが、これらの情報$V_1$～$V_4$は使用者側の品質システム管理者Ｓｍ、作業者Ｏｕによって改訂または修正可能である。

【００３１】また、前記各体系Ｄｖ１～Ｄｖ８における各検査項目$V_0$の内容の改訂または修正は、上述した指定の人Ｓｍ，Ｉｍ，Ｓｕ，Ｏｕによって検査項目$V_0$の追加および削除、さらに、各検査項目$V_0$の情報$V_1$～$V_4$の改訂または修正などを行うことができる。そして、コンピュータ３上で動作するバリデーションプログラムＰｖはこの改訂または修正の履歴を自動的に残す。

【００３２】一方、検査結果$V_5$を記録するときには、前記コンピュータ３上で動作するバリデーションプログラムＰｖは、各検査項目$V_0$の検査を行った後に、パスワード入力やＩＤ入力によって確認された帳票記録の責任者Ａｕ，Ａｍ，Ｉｍの指示を受けることによってのみ、検査結果を示す情報$V_5$を自動的に保存するように構成している。

【００３３】さらに、前記各体系Ｄｖ１～Ｄｖ８における各検査項目$V_0$の情報$V_1$～$V_5$の表示は誰でも行うことができるように構成している。情報の表示は、例えば、図１に示したような、ディスプレイ３ｄに画面表示することによって行うことができる。また、プリンタなどを接続することにより、用紙に印字することによって表示してもよいことは言うまでもない。

【００３４】次に、定期的に分析計を維持管理するための校正を行うときの例を説明する。以下の例は分析計の使用者Ｓｕ，Ｏｕ，Ａｕが行なう例を示しているが、以下の作業を製造者Ｓｍ，Ｉｍ，Ａｍが行うこともある。

【００３５】このとき、メンテナンスを含む定期検査および日常検査という時系列的体系のもとに、それぞれについての検査項目$V_0$、各項目毎にテスト方法、テストによる管理基準、テストに使用する標準機器、標準資料およびテスト結果の記録用帳票様式は予め定められており、または、各分析計３の使用者に合わせて、分析計３を使用する環境に合わせて改訂または修正している。

【００３６】そして、作業者が定期的なメンテナンスを含む定期検査および日常検査という時系列的体系の検査を行うことによって得られた検査結果を、帳票記録の責任者Ａｕ，Ａｍ，Ｉｍの指示によって行うことができる。このとき、バリデーションプログラムＰｖは、各検査項目$V_0$の情報$V_4$から帳票様式を呼び出し、データの自動取り込みや入力をし、検査結果の記録は帳票記録の責任者Ａｕ，Ａｍ，Ｉｍの承認を得なければ行えないようにする。また、保存された検査結果$V_5$はいかなる人も、字句の追加、削除が一切できないようになっている。

【００３７】なお、分析計１の維持・管理のために必要な校正、定期検査、日常検査については、実施するべき時期になると、ディスプレイ３ｄに画面表示することによって作業者に知らせるようにしている。すなわち、前記一覧表Ｔ中の実施するべき検査項目$V_0$の部分を点滅させるなどして、作業者に検査時期を通知することができる。また、本発明はこの検査時期の通知方法を限定するものではない。たとえば、分析不能にするなど、様々な方法が考えられる。

【００３８】以上のように構成することにより、分析計１の妥当性を確認するときはコンピュータ３を操作することで、行おうとする分析に関して品質を保証する複数の検査項目$V_0$とその検査結果$V_5$を含む各種情報を、極めて容易に取り出すことができる。また、同時に使用者が行なう分析法の妥当性も確認することができる。また、一旦保存された検査結果の情報$V_5$が変更されることがないだけでなく、記録忘れや紛失などの虞れが一切なくなる。すなわち、分析計１の品質の信頼性を確実に保証することができる。

【００３９】なお、上述した例においては、赤外線ガス分析計を例示しているが、本発明は分析計１の種類を限定するものではないことはいうまでもない。また、分析計１の構成が、分析部２とその情報処理装置３を別体にしたものに限られるものではなく、分析計１内に情報処理装置３を内蔵するものであってもよい。

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【００４０】さらに、本発明の分析計は一つの情報処理装置３によって多数の分析部２を制御するような分析システムを構成してもよい。この場合、情報処理装置３は各分析部２毎で別個に、その品質を保証する複数の検査項目$V_0$とその検査結果$V_5$を含む各種情報を保存する。

【００４１】加えて、前記バリデーションプログラムＰｖやそのプログラムで管理されるバリデーションデータＤｖは、コンピュータ読み取り可能な記録媒体に記録することにより、現行の分析計１の構成に容易に組み込むことができる。この場合、本発明の妥当性確認機能を有する分析計を極めて容易に構成できるという利点がある。

【００４２】

【発明の効果】以上説明したように、本発明によれば、妥当性確認に必要な各検査項目とその検査結果を含む各種情報を、既存の情報処理装置によって保管するので、分析計の構成を複雑にすることなく確実にデータを保管できる。つまり、使用者に手間をかけることなく品質を保証する複数の検査項目とその検査結果を含む各種情報を保管できるだけでなく、分析計の使用者による管理作業の実施忘れ、記録忘れ、保管忘れ、および、記録用紙の紛失を生じることがなく、確実に分析計の妥当性確認を行うことができる。

【図面の簡単な説明】

【図１】本発明の妥当性確認機能を有する分析計の一例の構成を示す概略図である。

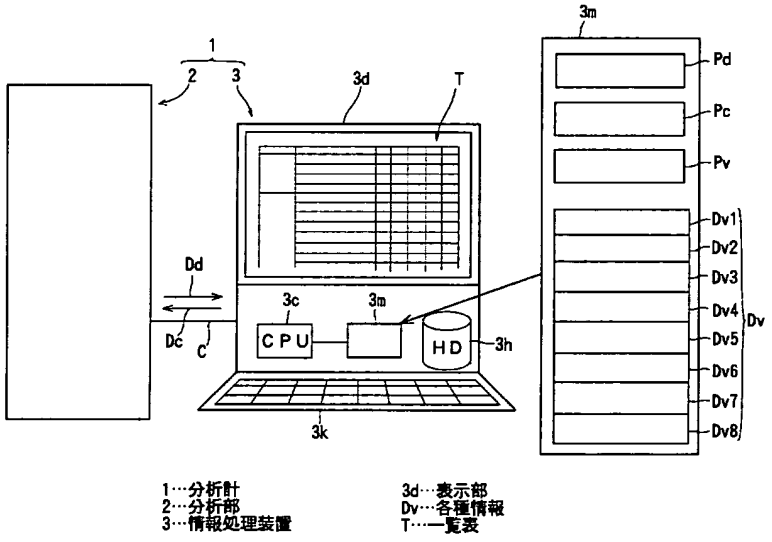
【図２】前記分析計の表示部に表示される各種情報の例を示す図である。

【図３】従来の分析計の構成および妥当性確認のために行なうことを開示する図である。

【符号の説明】

１…分析計、２…分析部、３…情報処理装置、３ｄ…表示部、Ｄｖ…各種情報、Ｔ…一覧表、$V_0$…検査項目、$V_5$…検査結果。

【図１】

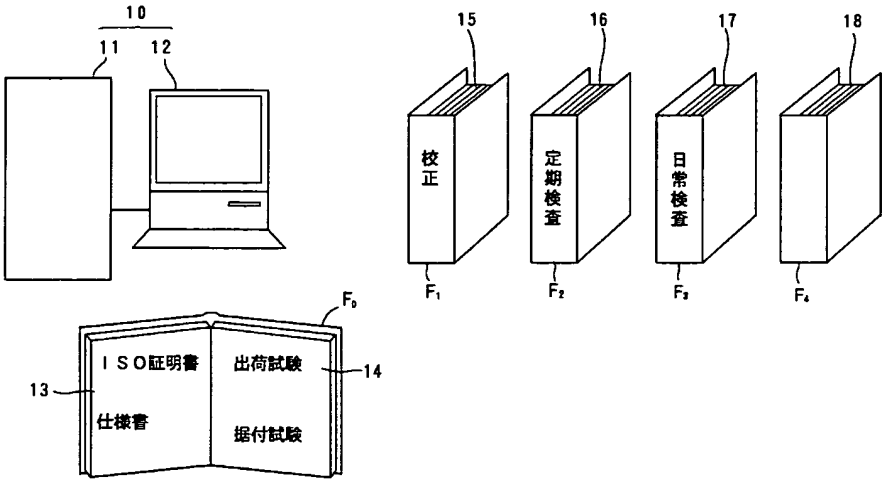


【図２】


| | 体系 | テスト項目 | テスト方法 | 管理基準 | 標準機器標準試料 | 帳票様式 | 検査結果 |
|---|---|---|---|---|---|---|---|
| Dv1 | 1.要求仕様 (ユーザ) | 分析試料： | | | | | Au |
| | | 分析範囲： | Su | Su | Su | | Au |
| | | 併行精度： | Su | Su | Su | | Au |
| | | | | | | | Au |
| Dv2 | 2.決定分析計型式 (メーカ) | 装置メーカ名： | | | | | |
| | | ＩＳＯ－９０００証明書 | | | | | Am |
| | | 型式名：　　製造番号： | | | | | |
| | | 分析方式： | | | | | |
| | | 使用１次標準 | | | | | Am |
| | | トレーサビリティ体系 | | | | | Am |
| | | 標準試料併行精度 | Sm | Sm | Sm | Im | Am |
| | | 標準試料直線性 | Sm | Sm | Sm | Im | Am |
| | | 分析元素と分析範囲 | Sm | Sm | Sm | Im | Am |
| | | 感度 | Sm | Sm | Sm | Im | Am |
| | | 燃焼炉最大温度 | Sm | Sm | Sm | Im | Am |
| | | 電源電圧変動と周波数変動 | Sm | Sm | Sm | Im | Am |
| | | 環境温度変化と環境湿度変化 | Sm | Sm | Sm | Im | Am |
| | | 酸素流量変化と酸素圧力変化 | Sm | Sm | Sm | Im | Am |
| | | 干渉影響 | Sm | Sm | Sm | Im | Am |
| | | 振動 | Sm | Sm | Sm | Im | Am |
| | | CEマーク；　　EMC試験； | | | | | Am |
| | | ソフトウェアValidation宣言書； | | | | | |
| | | | | | | | |
| Dv3 | 3. 出荷試験 (メーカ) | 計測部校正（標準ガス併行精度；標準ガス直線性） | Sm | Sm | Sm | Im | Im |
| | | 標準試料併行精度 | Sm | Sm | Sm | Im | Im |
| | | 校正証明： | Sm | Sm | Sm | Im | Im |
| | | トレーサビリティ証明； | Sm | Sm | Sm | Im | Im |
| | | | | | | | |
| Dv4 | 4. 据付試験 (メーカ) | 据付けの適格性（仕様、ドキュメント、環境・ユーティリティ） | Sm | Sm | Sm | Im | Im |
| | | 操作性の適格性（動作、機能） | Sm | Sm | Sm | Im | Im |
| | | 性能確認（併行精度） | Sm | Sm | Sm | Im | Im |
| | | ソフトチェック（改算チェック:SUMコード、日付、ファイルサイズ。標準データチェック） | Sm | Sm | Sm | Im | Im |
| | | | | | | | |
| Dv5 | 5. 校　正 (メーカ／ユーザ) | 性能（併行精度、直線性；標準ガス、標準試料） | SuSm | SuSm | SuSm | OuIm | AuIm |
| | | ソフトチェック（改算チェック:SUMコード、日付、ファイルサイズ。標準データチェック） | SuSm | SuSm | SuSm | OuIm | AuIm |
| | | 検量性（検量線作成） | SuSm | SuSm | SuSm | OuIm | AuIm |
| | | | | | | | |
| Dv6 | 6. 定期検査 (ユーザ) | メンテナンス | Su | Su | Su | Ou | Au |
| | | 性能適格性（併行精度） | Su | Su | Su | Ou | Au |
| | | | | | | | |
| Dv7 | 7. 日常検査 (ユーザ) | メンテナンス | Su | Su | Su | Ou | Au |
| | | 検量性適格性（ＱＣ試料分析：併行精度、正確さ） | Su | Su | Su | Ou | Au |
| | | | | | | | |
| Dv8 | 0. 分析法 (ユーザ) | 待ち時間：　　秒 | 特異性(抽出カーブ) | Su | Su | Su | Ou | Au |
| | | コンパレータレベル：　　% | 真度(対標準試料精度) | Su | Su | Su | Ou | Au |
| | | コンパレータ判定待ち時間：秒 | 精度（併行、室内） | Su | Su | Su | Ou | Au |
| | | 炉温度： | 検出限界(3.3*SD) | Su | Su | Su | Ou | Au |
| | | Step1：　～　℃、秒 | 定量限界(10*SD) | Su | Su | Su | Ou | Au |
| | | Step2：　～　℃、秒 | 直線性(精度範囲内 対標準試料精度内) | Su | Su | Su | Ou | Au |
| | | サンプル：　　gr. | 範囲(直線性の範囲) | Su | Su | Su | Ou | Au |
| | | 助燃剤：　、　gr. | 頑健性(試料量変化、炉温度変化) | Su | Su | Su | Ou | Au |

$V_0$…検査項目
$V_5$…検査結果

【図３】


10
11
12
15
16
17
18
校正
定期検査
日常検査
F1
F2
F3
F4
F0
ＩＳＯ証明書
出荷試験
仕様書
据付試験
13
14

# PATENT ABSTRACTS OF JAPAN

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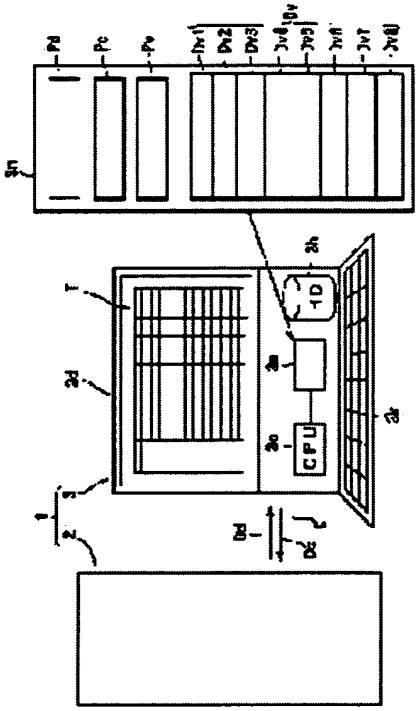
## (54) VALIDITY CONFIRMING METHOD FOR ANALYZER, ANALYZER WITH VALIDITY CONFIRMING FUNCTION, AND RECORDING MEDIUM RECORDING VALIDITY CONFIRMING PROGRAM OF ANALYZER

(57)Abstract:
PROBLEM TO BE SOLVED: To confirm the validity that an analyzer is adequate easily and reliably with no omission.
SOLUTION: In this validity confirming method, an analyzer 1 is provided with an analysis section 2 and an information processor 3 processing the analysis values from the analysis section 2, various information Dv including multiple inspection items for guaranteeing the quality on the analysis to be conducted and inspection results is recorded by the information processor 3 provided on the analyzer 1, the inspection results cannot be changed by the information processor 3, and the inspection items and inspection results are outputted to prove that the analyzer is adequate.

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CLAIMS

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[Claim(s)]
[Claim 1] The validation approach of the analyzer characterized by to prove that said analyzer is proper with outputting an inspection item and its inspection result while it records with two or more inspection items which guarantee quality about the analysis which it is going to perform in the analyzer equipped with the analyzor and the information processor which processes the analysis value from this analyzor, and the information processor which prepared the various information containing that inspection result in said analyzer and this information processor makes an inspection result modification impossible.
[Claim 2] The validation approach of the analyzer according to claim 1 which records the proofreading trial which the user of an analyzer performs as various information which guarantees the quality of said analyzer in addition to the decision analyzer form and the shipment trial which the manufacturer of an analyzer performs, and an installation trial, a periodic check, routine laboratory tests, and an analysis method.
[Claim 3] The validation approach of the analyzer according to claim 1 or 2 which records the information which shows the inspection approach, the information which shows management criteria, and the information which shows the standard device used for inspection, and a standard sample as said various information, respectively.
[Claim 4] The validation approach of an analyzer according to claim 3 of saving an inspection result with directions of the person in charge of document record after inspecting by the approach by which the inspection approach of the inspection item which corresponds by said information processor's dividing various information into an inspection item, displaying by making it a chart, and choosing the inspection item which a tester should perform from said chart was displayed, and the tester was displayed.
[Claim 5] The validation approach of an analyzer according to claim 3 or 4 of having left informational modification hysteresis while enabling it to change the information a user indicates the inspection approach to be, the information which shows management criteria, the information which shows the standard device used for inspection, and a standard sample, and the information which shows a document format in each inspection item of the proofreading trial which the user of said analyzer performs, a periodic check, routine laboratory tests, and an analysis method.
[Claim 6] The analyzer which has the validation function characterized by to have various information including two or more inspection items which guarantee quality about the analysis which it is going to perform in the analyzer equipped with the analyzor and the information processor which processes the analysis value from this analyzor, the record medium which record that inspection result on modification impossible, and in which computer R/W is possible, and the display which prove that said analyzer is proper with the output of the recorded information.
[Claim 7] The analyzer which has the validation function according to claim 6 in which the various information which guarantees the quality of said analyzer is the proofreading trial which the user of an analyzer performs in addition to the decision analyzer form, shipment trial, and installation trial which the manufacturer of an analyzer performs, a periodic check, routine laboratory tests, and an analysis method.
[Claim 8] The analyzer which has the validation function according to claim 6 or 7 in which said various information has the information which shows the inspection approach, the information which shows management criteria, and the information which shows the standard device used for inspection, and a standard sample, respectively.
[Claim 9] The analyzer which has the validation function according to claim 8 which constituted so that said information processor may save an inspection result with directions of the person in charge of document

record after inspecting by the approach by which the inspection approach of the inspection item which corresponds by said display's dividing various information into an inspection item, displaying by making it a chart, and choosing the inspection item which a tester should perform from said chart is displayed, and the tester was displayed on this display.

[Claim 10] The analyzer which has the validation function according to claim 8 or 9 which constituted so that it may leave informational modification hysteresis while could change the information which shows the inspection approach, the information which shows management criteria, the information which shows the standard device used for inspection, and a standard sample, and the information which shows a document format by the user in each inspection item of the proofreading trial which the user of said analyzer performs, a periodic check, routine laboratory tests, and an analysis method.

[Claim 11] It is the program included in said information processor of the analyzer equipped with the analyzor and the information processor which processes the analysis value from this analyzor. While recording the various information containing two or more inspection items which guarantee quality about the analysis which it is going to perform, and the inspection result of those on the record medium which can be written with said information processor and making the recorded inspection result into modification impossible The record medium which recorded the validation program of the analyzer characterized by enabling certification of said analyzer being proper with the output of various information and in which computer reading is possible.

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DETAILED DESCRIPTION

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[Detailed Description of the Invention]
[0001]
[Field of the Invention] This invention relates to the record medium which recorded the validation program of the analyzer which has the validation approach of an analyzer, and a validation function, and an analyzer.
[0002]
[Description of the Prior Art] Conventionally, an information processor may be built into an analyzer and such an analyzer was processing control of the analyzor which consists of a detector which detects the various quantity of states of the measuring object as an analysis value, and the analysis value acquired from this analyzor with the information processor (computer). That is, offering a more useful analyzer is performed by performing reading of the analysis value from the analyzor, an operation, transfer, etc. with this information processor.
[0003] Moreover, in recent years, in order to guarantee the dependability of an analysis value and the validity of an analyzer which were measured by said analyzer, performing validation which checks the dependability of the measured value obtained from the analyzer and the justification of an analysis method is increasingly called for on a scale of worldwide. When using these analyzers with commercial liberalization also overseas especially, it may be necessary to prove the validity of an analysis value and an analyzer according to the criteria of the validation defined by the law of each country.
[0004] Drawing 3 is drawing explaining the validation approach in the conventional analyzer 10. The conventional analyzer 10 consists of analyzor 11 and an information processor 12 (computer) connected to this analyzor 11 in drawing 3 . Moreover, this analyzer 10 is the file F0 which keeps the document 13 which indicated various decision analyzer form of an analyzer 10, such as specification and an ISO certificate, at the time of manufacture. It is in the condition which stored the document 14 which indicated the contents of the shipment trial which has, for example, is performed at the time of shipment of each analyzer 10, and the contents of the installation trial, and is kept by the manufacturer side of an analyzer 10.
[0005] Files F1, F2, and F3 which keep the documents 15, 16, and 17 which, on the other hand, indicated the contents of the proofreading trial which a user performs in the user side of an analyzer 10, a periodic check, and routine laboratory tests It is kept, respectively. these files F1, F2, and F3 **** -- what recorded details, such as what is used as the test approach of a proofreading trial, a periodic check, and routine laboratory tests, management criteria and a standard device, or a standard sample, respectively, was stored, and the analyzer 10 was managed, referring to these.
[0006] Moreover, file F4 which keeps the document 18 which recorded the analysis method in addition to these He prepares and is also trying to leave record of each measurement performed with the analyzer 10. Therefore, when it will be checked once in 1 whether the analysis value by said analyzer 10 is appropriate, it is said file F1 -F4. What is necessary is to use and just to check documents 15-18. Moreover, it is the file F0 which the manufacturer is keeping when checking the validity of the analyzer 10 in the time of being introduced. It can check.
[0007]
[Problem(s) to be Solved by the Invention] However, in managing by the approach mentioned above, in order to prove analytic validity in addition to the specifications of huge amounts, such as management criteria, documents 13-18 had to perform the operation, propriety decision, and record of management based on management criteria, and these had to be kept certainly. Therefore, many documents 13-18 are needed and they are these File F0 -F4 Although it needed to be kept with a note etc., a management failure, loss, etc. may

have taken place further keep being an operation failure of a user, record, etc. Moreover, since record of the inspection in the phase at the time before shipment of an analyzer 10 of installation is saved by the manufacturer side, it also had the fault that it could not check by the user side.
[0008] The check of validity with a proper analyzer does not escape from the place which this invention is made, taking an above-mentioned matter into consideration, and is made into the purpose, and is to offer [ easy and ] the record medium which recorded the validation program of the analyzer which has the validation approach of the analyzer which can carry out certain, and a validation function, and an analyzer.
[0009]
[Means for Solving the Problem] In order to attain the above-mentioned purpose, the validation approach of the analyzer of this invention In the analyzer equipped with the analyzor and the information processor which processes the analysis value from this analyzor While it records with two or more inspection items which guarantee quality about the analysis which it is going to perform, and the information processor which prepared the various information containing that inspection result in said analyzer and this information processor makes an inspection result modification impossible It is characterized by proving that said analyzer is proper with outputting an inspection item and its inspection result.
[0010] Therefore, since the various information containing required for validation each inspection item and its inspection result is kept with the existing information processor, data can be kept certainly, without complicating the configuration of an analyzer. That is, it not only does not apply time and effort to a user, but an operation failure of the management activity by the user of an analyzer, a record failure, a storage failure, and loss of a record form do not arise, and it can perform validation certainly. In addition, in this invention, the proofreading activity of an analyzer and tuning are also included in the activity expressed as inspection.
[0011] Moreover, when recording the proofreading trial which the user of an analyzer performs, a periodic check, routine laboratory tests, and an analysis method as various information which guarantees the quality of said analyzer in addition to the decision analyzer form and the shipment trial which the manufacturer of an analyzer performs, and an installation trial, the information as a result of the shipment trial in the phase at the shipment front of an analyzer or the time of installation, an installation trial, and a proofreading trial etc. can also be referred to for validation. That is, this analyzer can be used in all the areas where the criteria for validation differ.
[0012] furthermore, in recording the information which shows the inspection approach, the information which shows management criteria, and the information which shows the standard device used for inspection, and a standard sample as said various information, respectively As data by the side of a user required at the time of installation of an analyzer, to the inspection approach of an analyzer, and management criteria and a pan Since each information, such as a standard device used for inspection of an analyzer and a standard sample, is inputted and saved at the information processor of an analyzer, it becomes unnecessary to keep in a form etc. the specifications of huge amounts, such as management criteria currently prepared separately conventionally.

[0013] By said information processor's dividing various information into an inspection item, displaying by making it a chart, and choosing the inspection item which a tester should perform from said chart In saving an inspection result with directions of the person in charge of document record after inspecting by the approach by which the inspection approach of the corresponding inspection item was displayed, and the tester was displayed Since the directions of the inspection approach which are need and which should be performed by the way can be obtained very easily, while being able to lessen time and effort, even if who inspects, it can inspect on the same conditions. That is, validation of an analyzer can be performed more certainly. In addition, in this invention, the operator who performs proofreading activity of an analyzer and tuning is also contained in those who express it as a tester.
[0014] In each inspection item of the proofreading trial which the user of said analyzer performs, a periodic check, routine laboratory tests, and an analysis method While a user enables it to change the information which shows the inspection approach, the information which shows management criteria, the information which shows the standard device used for inspection, and a standard sample, and the information which shows a document format While a degree of freedom increases since the contents of a proofreading trial, a periodic check, routine laboratory tests, and the analysis method can be changed according to the need for a user when leaving informational modification hysteresis, since modification hysteresis remains, it can leave information required for validation.

[0015] The analyzer which has the validation function of this invention is characterized by having various information including two or more inspection items which guarantee quality about the analysis which it is going to perform, the record medium which records the inspection result on modification impossible and in which computer R/W is possible, and the display which proves that said analyzer is proper with the output of the recorded information. That is, required all of validation can be managed with the information processor attached in the analyzer, and an analyzer and the dependability of analysis by this analyzer can be guaranteed.
[0016] The various information which guarantees the quality of said analyzer may be the proofreading trial which the user of an analyzer performs in addition to the decision analyzer form, shipment trial, and installation trial which the manufacturer of an analyzer performs, a periodic check, routine laboratory tests, and an analysis method.
[0017] Moreover, said various information may have the information which shows the inspection approach, the information which shows management criteria, and the information which shows the standard device used for inspection, and a standard sample, respectively. In this case, the inspection approach of the inspection item which corresponds by said display's dividing various information into an inspection item, displaying by making it a chart, and choosing the inspection item which a tester should perform from said chart is displayed, and after a tester inspects by the approach displayed on this display, you may constitute so that said information processor may save an inspection result with directions of the person in charge of document record.
[0018] Furthermore, in each inspection item of the proofreading trial which the user of said analyzer performs, a periodic check, routine laboratory tests, and an analysis method, while being able to change the information which shows the inspection approach, the information which shows management criteria, the information which shows the standard device used for inspection, and a standard sample, and the information which shows a document format by the user, you may constitute so that it may leave informational modification hysteresis.
[0019] The record medium which recorded the validation program of the analyzer of this invention is characterized by to enable certification of said analyzer being proper with the output of various information while it records the various information containing two or more inspection items which guarantee quality about the analysis which it is going to perform, and the inspection result of those on the record medium which can be written with said information processor and makes modification impossible the recorded inspection result.
[0020]
[Embodiment of the Invention] Drawing 1 is drawing showing an example of an analyzer 1 which has the validation function of this invention. In drawing 1 , 2 is the analyzor which calculates the content of the minute amount carbon contained in a measuring object sample, or sulfur by the infrared gas analysis of the gas which burned, and the information processor 3 (henceforth a computer) by which 3 is connected to this analyzor 2. The computer 3 has CPU3c, memory 3m, hard disk 3h that is an example of an auxiliary storage unit, display 3d which is an example of a display, and keyboard 3k. In addition, it cannot be overemphasized that this invention is not what limits the class of analyzer 2.
[0021] Said computer 3 executes the data-processing program Pd which inputs the measured value Dd from the analyzor 2 through telecommunication cable C, and processes this, the control program Pc which outputs the control command Dc which controls the analyzor 2, and the validation program Pv (henceforth a validation program) proving said analyzer 2 being proper. Each programs Pd, Pc, and Pv are executed, where it read all from the record medium which can computer read hard disk 3h etc. and they are written in memory 3m.
[0022] Moreover, Dv is validation data saved by said BARIDEDEYON program Pv. In addition, this validation data Dv is not only saved in memory 3, but is saved at auxiliary storage units, such as hard disk 3h and nonvolatile memory, and he is trying not to extinguish those contents.
[0023] Drawing 2 shows the example of a display of the screen displayed on said display 3d, and displays the chart T showing two or more inspection items which guarantee quality about the analysis which it is going to perform, and the inspection result of those in this example. Moreover, this chart T shows the contents of processing by said validation program Pv. As shown in Chart T, said validation data Dv have the system roughly divided into eight.
[0024] That is, said validation data Dv are classified into the shipment trial Dv3 performed when supplying a user the decision analyzer form Dv2 of the analyzer 1 which the manufacturer defined corresponding to the requirement specification Dv1 and this to the analyzer 1 by the side of a user, and an analyzer 1, the installation trial Dv4, the proofreading trial Dv5 performed by the user side, a periodic check Dv6, routine laboratory tests Dv7, and the analysis method Dv8 that shows the analytical method which a user defines.

[0025] As for each of the validation data Dv1-Dv8 of each of said system, two or more items are prepared according to the class of analyzer 1. for example, the case of this example -- as the decision analyzer form Dv2 -- not only various information items, such as an acquisition certificate of an ISO quality system, and a software declaration, but inspection items V0, such as standard sample concurrency precision, standard sample linearity, an analytical element and the analysis range, sensibility - vibration, It has.
[0026] Moreover, said validation data are each inspection item V0. The information V1 which corresponds and shows the inspection approach, the information V2 which shows management criteria, the information V3 which shows the standard device used for inspection, and a standard sample, and information V4 which shows the format of the document which indicates an inspection result And information V5 which specifies the person in charge of document record It has.
[0027] each inspection item V0 of the decision analyzer form Dv2 among eight systems mentioned above as shown in said chart T, the shipment trial Dv3, the installation trial Dv4, and the proofreading trial Dv5 The information V1 which shows the inspection approach, management criteria, the standard device used for inspection, and a standard sample, and V2 and V3 It is the contents at the shipment time of an analyzer 1, they are defined by the manufacturer, and this is recorded on memory 3m, 3h of external storage etc., etc. (preservation). Moreover, each above-mentioned inspection item V0 Information V1, V2, and V3 It expresses that the contents are what is saved, the tester, i.e., quality system administrator Sm, for example, by the side of a manufacturer, by writing it as "Sm" in Chart T. (Also setting in each following item the same)
[0028] In addition, each above-mentioned inspection item V0 Information V4 which shows the document format which can be set Record is performed by the device tester Im by the side of a manufacturer. Moreover, said inspection item V0 Information V5 which shows an inspection result Record is performed by the person in charge Am of document record, i.e., the total responsibility person by the side of a manufacturer, and the device tester Im by the side of a manufacturer.
[0029] Each inspection item V0 of one side, requirement specification Dv1, the proofreading trial Dv5, a periodic check Dv6, routine laboratory tests Dv7, and an analysis method Dv8 Information V1, V2, and V3 The contents are defined by Tester Su, i.e., the system administrator, and Operator Ou by the side of the user of an analyzer 1, and this is saved. Moreover, each inspection item V0 Information V5 which shows an inspection result Record is performed by directions of the total responsibility person Au who is a person in charge of the document record by the side of a user.
[0030] In addition, it sets for the example shown in the above-mentioned chart T, and is information V1 -V4 of each inspection item V0 of the proofreading trial Dv5. The contents are these information V1 -V4, although beforehand set by quality system administrator Sm and the device tester Im by the side of the manufacturer of an analyzer 1 at the time of shipment. Revision or correction by quality system administrator Sm by the side of a user and Operator Ou is possible.
[0031] Moreover, each inspection item V0 in said each systems Dv1-Dv8 Revision or correction of the contents is an inspection item V0 by the men Sm, Im, Su, and Ou of the assignment mentioned above. It is each inspection item V0 to an addition and deletion, and a pan. Information V1 -V4 Revision or correction can be made. And the validation program Pv which operates on a computer 3 leaves the hysteresis of this revision or correction automatically.
[0032] On the other hand, it is an inspection result V5. The validation program Pv which operates on said computer 3 when recording is each inspection item V0. Information V5 which shows an inspection result only by receiving directions of the persons in charge Au, Am, and Im of the document record checked by the password input or ID input after inspecting It constitutes so that it may save automatically.
[0033] Furthermore, each inspection item V0 in said each systems Dv1-Dv8 It constitutes so that anyone can perform the display of information V1 -V5. Informational presenting can be performed by carrying out a screen display to display 3d as shown in drawing 1 . Moreover, it cannot be overemphasized by connecting a printer etc. that you may display by printing in a form.
[0034] Next, the example when performing the proofreading for carrying out the maintenance of the analyzer periodically is explained. Although the following examples show the example which the users Su, Ou, and Au of an analyzer perform, Manufacturers Sm, Im, and Am may do the following activities.
[0035] At this time, the inspection item V0 about each, management criteria according to the test approach and a test the whole item, the standard device used for a test, standard data, and the document format for record of a test result are revised or corrected to the basis of the serial system of a periodic check and

routine laboratory tests including a maintenance according to the environment which is defined beforehand or uses an analyzer 3 according to the user of each analyzer 3.

[0036] And directions of the persons in charge Au, Am, and Im of document record can perform the inspection result obtained when an operator inspected the serial system of a periodic check and routine laboratory tests including a periodical maintenance. this time -- a validation program Pv -- each inspection item V0 Information V4 from -- a document format is called and automatic incorporation and input of data are carried out, and if record of an inspection result does not acquire the approval of the persons in charge Au, Am, and Im of document record, it prevents from performing it Moreover, saved inspection result V5 Any men have come to be unable to do addition of a token, and deletion at all.

[0037] In addition, if the stage which should be carried out comes, he is trying to tell an operator by carrying out a screen display to display 3d about proofreading required for maintenance and management of an analyzer 1, a periodic check, and routine laboratory tests. Namely, inspection item V0 which should carry out in said chart T A part can be blinked and an operator can be notified of an inspection stage. Moreover, this invention does not limit the notice approach of this inspection stage. For example, various approaches, such as making it analysis impossible, can be considered.

[0038] By constituting as mentioned above, they are two or more inspection items V0 which guarantee quality by operating a computer 3 when checking the validity of an analyzer 1 about the analysis which it is going to perform. The inspection result V5 The various information to include can be taken out very easily. Moreover, the validity of the analysis method which a user performs to coincidence can also be checked. Moreover, information V5 on the once saved inspection result It is not not only changed, but fear, such as a record failure and loss, is lost entirely. That is, the dependability of the quality of an analyzer 1 can be guaranteed certainly.

[0039] In addition, in the example mentioned above, although the infrared gas analyzer is illustrated, it cannot be overemphasized that this invention is not what limits the class of analyzer 1. Moreover, the configuration of an analyzer 1 is not restricted to what used the analyzor 2 and its information processor 3 as another object, and may build in an information processor 3 in an analyzer 1.

[0040] Furthermore, the analyzer of this invention may constitute an analysis system which controls many analyzor 2 by one information processor 3. In this case, information processors 3 are two or more inspection items V0 which guarantee that quality separately the whole analyzor 2. The various information containing that inspection result V5 is saved.

[0041] In addition, the validation data Dv managed by said validation program Pv and its program are easily incorporable into the configuration of the present analyzer 1 by recording on the record medium in which computer reading is possible. In this case, there is an advantage that the analyzer which has the validation function of this invention can be constituted very easily.

[0042]

[Effect of the Invention] Since the various information containing required for validation each inspection item and its inspection result is kept with the existing information processor according to this invention as explained above, data can be kept certainly, without complicating the configuration of an analyzer. That is, without applying time and effort to a user, it does not produce an operation failure of the management activity by the user of an analyzer, a record failure, a storage failure, and loss of a record form, and it not only can keep the various information containing two or more inspection items which guarantee quality, and the inspection result of those, but can perform validation of an analyzer certainly.

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TECHNICAL FIELD

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[Field of the Invention] This invention relates to the record medium which recorded the validation program of the analyzer which has the validation approach of an analyzer, and a validation function, and an analyzer.

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PRIOR ART

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[Description of the Prior Art] Conventionally, an information processor may be built into an analyzer and such an analyzer was processing control of the analyzor which consists of a detector which detects the various quantity of states of the measuring object as an analysis value, and the analysis value acquired from this analyzor with the information processor (computer). That is, offering a more useful analyzer is performed by performing reading of the analysis value from the analyzor, an operation, transfer, etc. with this information processor.
[0003] Moreover, in recent years, in order to guarantee the dependability of an analysis value and the validity of an analyzer which were measured by said analyzer, performing validation which checks the dependability of the measured value obtained from the analyzer and the justification of an analysis method is increasingly called for on a scale of worldwide. When using these analyzers with commercial liberalization also overseas especially, it may be necessary to prove the validity of an analysis value and an analyzer according to the criteria of the validation defined by the law of each country.
[0004] Drawing 3 is drawing explaining the validation approach in the conventional analyzer 10. The conventional analyzer 10 consists of analyzor 11 and an information processor 12 (computer) connected to this analyzor 11 in drawing 3 . Moreover, this analyzer 10 is the file F0 which keeps the document 13 which indicated various decision analyzer form of an analyzer 10, such as specification and an ISO certificate, at the time of manufacture. It is in the condition which stored the document 14 which indicated the contents of the shipment trial which has, for example, is performed at the time of shipment of each analyzer 10, and the contents of the installation trial, and is kept by the manufacturer side of an analyzer 10.
[0005] Files F1, F2, and F3 which keep the documents 15, 16, and 17 which, on the other hand, indicated the contents of the proofreading trial which a user performs in the user side of an analyzer 10, a periodic check, and routine laboratory tests It is kept, respectively. these files F1, F2, and F3 **** -- what recorded details, such as what is used as the test approach of a proofreading trial, a periodic check, and routine laboratory tests, management criteria and a standard device, or a standard sample, respectively, was stored, and the analyzer 10 was managed, referring to these.
[0006] Moreover, file F4 which keeps the document 18 which recorded the analysis method in addition to these He prepares and is also trying to leave record of each measurement performed with the analyzer 10. Therefore, when it will be checked once in 1 whether the analysis value by said analyzer 10 is appropriate, it is said file F1 -F4. What is necessary is to use and just to check documents 15-18. Moreover, it is the file F0 which the manufacturer is keeping when checking the validity of the analyzer 10 in the time of being introduced. It can check.

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## EFFECT OF THE INVENTION

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[Effect of the Invention] Since the various information containing required for validation each inspection item and its inspection result is kept with the existing information processor according to this invention as explained above, data can be kept certainly, without complicating the configuration of an analyzer. That is, without applying time and effort to a user, it does not produce an operation failure of the management activity by the user of an analyzer, a record failure, a storage failure, and loss of a record form, and it not only can keep the various information containing two or more inspection items which guarantee quality, and the inspection result of those, but can perform validation of an analyzer certainly.

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TECHNICAL PROBLEM

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[Problem(s) to be Solved by the Invention] However, in managing by the approach mentioned above, in order to prove analytic validity in addition to the specifications of huge amounts, such as management criteria, documents 13-18 had to perform the operation, propriety decision, and record of management based on management criteria, and these had to be kept certainly. Therefore, many documents 13-18 are needed and they are these File F0 -F4 Although it needed to be kept with a note etc., a management failure, loss, etc. may have taken place further keep being an operation failure of a user, record, etc. Moreover, since record of the inspection in the phase at the time before shipment of an analyzer 10 of installation is saved by the manufacturer side, it also had the fault that it could not check by the user side.
[0008] The check of validity with a proper analyzer does not escape from the place which this invention is made, taking an above-mentioned matter into consideration, and is made into the purpose, and is to offer [ easy and ] the record medium which recorded the validation program of the analyzer which has the validation approach of the analyzer which can carry out certain, and a validation function, and an analyzer.

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MEANS

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[Means for Solving the Problem] In order to attain the above-mentioned purpose, the validation approach of the analyzer of this invention In the analyzer equipped with the analyzor and the information processor which processes the analysis value from this analyzor While it records with two or more inspection items which guarantee quality about the analysis which it is going to perform, and the information processor which prepared the various information containing that inspection result in said analyzer and this information processor makes an inspection result modification impossible It is characterized by proving that said analyzer is proper with outputting an inspection item and its inspection result.
[0010] Therefore, since the various information containing required for validation each inspection item and its inspection result is kept with the existing information processor, data can be kept certainly, without complicating the configuration of an analyzer. That is, it not only does not apply time and effort to a user, but an operation failure of the management activity by the user of an analyzer, a record failure, a storage failure, and loss of a record form do not arise, and it can perform validation certainly. In addition, in this invention, the proofreading activity of an analyzer and tuning are also included in the activity expressed as inspection.
[0011] Moreover, when recording the proofreading trial which the user of an analyzer performs, a periodic check, routine laboratory tests, and an analysis method as various information which guarantees the quality of said analyzer in addition to the decision analyzer form and the shipment trial which the manufacturer of an analyzer performs, and an installation trial, the information as a result of the shipment trial in the phase at the shipment front of an analyzer or the time of installation, an installation trial, and a proofreading trial etc. can also be referred to for validation. That is, this analyzer can be used in all the areas where the criteria for validation differ.
[0012] furthermore, in recording the information which shows the inspection approach, the information which shows management criteria, and the information which shows the standard device used for inspection, and a standard sample as said various information, respectively As data by the side of a user required at the time of installation of an analyzer, to the inspection approach of an analyzer, and management criteria and a pan Since each information, such as a standard device used for inspection of an analyzer and a standard sample, is inputted and saved at the information processor of an analyzer, it becomes unnecessary to keep in a form etc. the specifications of huge amounts, such as management criteria currently prepared separately conventionally.

[0013] By said information processor's dividing various information into an inspection item, displaying by making it a chart, and choosing the inspection item which a tester should perform from said chart In saving an inspection result with directions of the person in charge of document record after inspecting by the approach by which the inspection approach of the corresponding inspection item was displayed, and the tester was displayed Since the directions of the inspection approach which are need and which should be performed by the way can be obtained very easily, while being able to lessen time and effort, even if who inspects, it can inspect on the same conditions. That is, validation of an analyzer can be performed more certainly. In addition, in this invention, the operator who performs proofreading activity of an analyzer and tuning is also contained in those who express it as a tester.
[0014] In each inspection item of the proofreading trial which the user of said analyzer performs, a periodic check, routine laboratory tests, and an analysis method While a user enables it to change the information which shows the inspection approach, the information which shows management criteria, the information which shows the standard device used for inspection, and a standard sample, and the information which shows a document format While a degree of freedom increases since the contents of a proofreading trial, a periodic

check, routine laboratory tests, and the analysis method can be changed according to the need for a user when leaving informational modification hysteresis, since modification hysteresis remains, it can leave information required for validation.

[0015] The analyzer which has the validation function of this invention is characterized by having various information including two or more inspection items which guarantee quality about the analysis which it is going to perform, the record medium which records the inspection result on modification impossible and in which computer R/W is possible, and the display which proves that said analyzer is proper with the output of the recorded information. That is, required all of validation can be managed with the information processor attached in the analyzer, and an analyzer and the dependability of analysis by this analyzer can be guaranteed.

[0016] The various information which guarantees the quality of said analyzer may be the proofreading trial which the user of an analyzer performs in addition to the decision analyzer form, shipment trial, and installation trial which the manufacturer of an analyzer performs, a periodic check, routine laboratory tests, and an analysis method.

[0017] Moreover, said various information may have the information which shows the inspection approach, the information which shows management criteria, and the information which shows the standard device used for inspection, and a standard sample, respectively. In this case, the inspection approach of the inspection item which corresponds by said display's dividing various information into an inspection item, displaying by making it a chart, and choosing the inspection item which a tester should perform from said chart is displayed, and after a tester inspects by the approach displayed on this display, you may constitute so that said information processor may save an inspection result with directions of the person in charge of document record.

[0018] Furthermore, in each inspection item of the proofreading trial which the user of said analyzer performs, a periodic check, routine laboratory tests, and an analysis method, while being able to change the information which shows the inspection approach, the information which shows management criteria, the information which shows the standard device used for inspection, and a standard sample, and the information which shows a document format by the user, you may constitute so that it may leave informational modification hysteresis.

[0019] The record medium which recorded the validation program of the analyzer of this invention is characterized by to enable certification of said analyzer being proper with the output of various information while it records the various information containing two or more inspection items which guarantee quality about the analysis which it is going to perform, and the inspection result of those on the record medium which can be written with said information processor and makes modification impossible the recorded inspection result.

[0020]

[Embodiment of the Invention] Drawing 1 is drawing showing an example of an analyzer 1 which has the validation function of this invention. In drawing 1 , 2 is the analyzor which calculates the content of the minute amount carbon contained in a measuring object sample, or sulfur by the infrared gas analysis of the gas which burned, and the information processor 3 (henceforth a computer) by which 3 is connected to this analyzor 2. The computer 3 has CPU3c, memory 3m, hard disk 3h that is an example of an auxiliary storage unit, display 3d which is an example of a display, and keyboard 3k. In addition, it cannot be overemphasized that this invention is not what limits the class of analyzer 2.

[0021] Said computer 3 executes the data-processing program Pd which inputs the measured value Dd from the analyzor 2 through telecommunication cable C, and processes this, the control program Pc which outputs the control command Dc which controls the analyzor 2, and the validation program Pv (henceforth a validation program) proving said analyzer 2 being proper. Each programs Pd, Pc, and Pv are executed, where it read all from the record medium which can computer read hard disk 3h etc. and they are written in memory 3m.

[0022] Moreover, Dv is validation data saved by said BARIDEDEYON program Pv. In addition, this validation data Dv is not only saved in memory 3, but is saved at auxiliary storage units, such as hard disk 3h and nonvolatile memory, and he is trying not to extinguish those contents.

[0023] Drawing 2 shows the example of a display of the screen displayed on said display 3d, and displays the chart T showing two or more inspection items which guarantee quality about the analysis which it is going to perform, and the inspection result of those in this example. Moreover, this chart T shows the contents of processing by said validation program Pv. As shown in Chart T, said validation data Dv have the system roughly divided into eight.

[0024] That is, said validation data Dv are classified into the shipment trial Dv3 performed when supplying a user the decision analyzer form Dv2 of the analyzer 1 which the manufacturer defined corresponding to the

requirement specification Dv1 and this to the analyzer 1 by the side of a user, and an analyzer 1, the installation trial Dv4, the proofreading trial Dv5 performed by the user side, a periodic check Dv6, routine laboratory tests Dv7, and the analysis method Dv8 that shows the analytical method which a user defines.
[0025] As for each of the validation data Dv1-Dv8 of each of said system, two or more items are prepared according to the class of analyzer 1. for example, the case of this example -- as the decision analyzer form Dv2 -- not only various information items, such as an acquisition certificate of an ISO quality system, and a software declaration, but inspection items V0, such as standard sample concurrency precision, standard sample linearity, an analytical element and the analysis range, sensibility - vibration, It has.
[0026] Moreover, said validation data are each inspection item V0. The information V1 which corresponds and shows the inspection approach, the information V2 which shows management criteria, the information V3 which shows the standard device used for inspection, and a standard sample, and information V4 which shows the format of the document which indicates an inspection result And information V5 which specifies the person in charge of document record It has.
[0027] each inspection item V0 of the decision analyzer form Dv2 among eight systems mentioned above as shown in said chart T, the shipment trial Dv3, the installation trial Dv4, and the proofreading trial Dv5 The information V1 which shows the inspection approach, management criteria, the standard device used for inspection, and a standard sample, and V2 and V3 It is the contents at the shipment time of an analyzer 1, they are defined by the manufacturer, and this is recorded on memory 3m, 3h of external storage etc., etc. (preservation). Moreover, each above-mentioned inspection item V0 Information V1, V2, and V3 It expresses that the contents are what is saved, the tester, i.e., quality system administrator Sm, for example, by the side of a manufacturer, by writing it as "Sm" in Chart T. (Also setting in each following item the same)
[0028] In addition, each above-mentioned inspection item V0 Information V4 which shows the document format which can be set Record is performed by the device tester Im by the side of a manufacturer. Moreover, said inspection item V0 Information V5 which shows an inspection result Record is performed by the person in charge Am of document record, i.e., the total responsibility person by the side of a manufacturer, and the device tester Im by the side of a manufacturer.
[0029] Each inspection item V0 of one side, requirement specification Dv1, the proofreading trial Dv5, a periodic check Dv6, routine laboratory tests Dv7, and an analysis method Dv8 Information V1, V2, and V3 The contents are defined by Tester Su, i.e., the system administrator, and Operator Ou by the side of the user of an analyzer 1, and this is saved. Moreover, each inspection item V0 Information V5 which shows an inspection result Record is performed by directions of the total responsibility person Au who is a person in charge of the document record by the side of a user.
[0030] In addition, it sets for the example shown in the above-mentioned chart T, and is information V1 -V4 of each inspection item V0 of the proofreading trial Dv5. The contents are these information V1 -V4, although beforehand set by quality system administrator Sm and the device tester Im by the side of the manufacturer of an analyzer 1 at the time of shipment. Revision or correction by quality system administrator Sm by the side of a user and Operator Ou is possible.
[0031] Moreover, each inspection item V0 in said each systems Dv1-Dv8 Revision or correction of the contents is an inspection item V0 by the men Sm, Im, Su, and Ou of the assignment mentioned above. It is each inspection item V0 to an addition and deletion, and a pan. Information V1 -V4 Revision or correction can be made. And the validation program Pv which operates on a computer 3 leaves the hysteresis of this revision or correction automatically.
[0032] On the other hand, it is an inspection result V5. The validation program Pv which operates on said computer 3 when recording is each inspection item V0. Information V5 which shows an inspection result only by receiving directions of the persons in charge Au, Am, and Im of the document record checked by the password input or ID input after inspecting It constitutes so that it may save automatically.
[0033] Furthermore, each inspection item V0 in said each systems Dv1-Dv8 It constitutes so that anyone can perform the display of information V1 -V5. Informational presenting can be performed by carrying out a screen display to display 3d as shown in drawing 1 . Moreover, it cannot be overemphasized by connecting a printer etc. that you may display by printing in a form.
[0034] Next, the example when performing the proofreading for carrying out the maintenance of the analyzer periodically is explained. Although the following examples show the example which the users Su, Ou, and Au of an analyzer perform, Manufacturers Sm, Im, and Am may do the following activities.

[0035] At this time, the inspection item V0 about each, management criteria according to the test approach and a test the whole item, the standard device used for a test, standard data, and the document format for record of a test result are revised or corrected to the basis of the serial system of a periodic check and routine laboratory tests including a maintenance according to the environment which is defined beforehand or uses an analyzer 3 according to the user of each analyzer 3.
[0036] And directions of the persons in charge Au, Am, and Im of document record can perform the inspection result obtained when an operator inspected the serial system of a periodic check and routine laboratory tests including a periodical maintenance. this time -- a validation program Pv -- each inspection item V0 Information V4 from -- a document format is called and automatic incorporation and input of data are carried out, and if record of an inspection result does not acquire the approval of the persons in charge Au, Am, and Im of document record, it prevents from performing it Moreover, saved inspection result V5 Any men have come to be unable to do addition of a token, and deletion at all.
[0037] In addition, if the stage which should be carried out comes, he is trying to tell an operator by carrying out a screen display to display 3d about proofreading required for maintenance and management of an analyzer 1, a periodic check, and routine laboratory tests. Namely, inspection item V0 which should carry out in said chart T A part can be blinked and an operator can be notified of an inspection stage. Moreover, this invention does not limit the notice approach of this inspection stage. For example, various approaches, such as making it analysis impossible, can be considered.
[0038] By constituting as mentioned above, they are two or more inspection items V0 which guarantee quality by operating a computer 3 when checking the validity of an analyzer 1 about the analysis which it is going to perform. The inspection result V5 The various information to include can be taken out very easily. Moreover, the validity of the analysis method which a user performs to coincidence can also be checked. Moreover, information V5 on the once saved inspection result It is not not only changed, but fear, such as a record failure and loss, is lost entirely. That is, the dependability of the quality of an analyzer 1 can be guaranteed certainly.
[0039] In addition, in the example mentioned above, although the infrared gas analyzer is illustrated, it cannot be overemphasized that this invention is not what limits the class of analyzer 1. Moreover, the configuration of an analyzer 1 is not restricted to what used the analyzor 2 and its information processor 3 as another object, and may build in an information processor 3 in an analyzer 1.
[0040] Furthermore, the analyzer of this invention may constitute an analysis system which controls many analyzor 2 by one information processor 3. In this case, information processors 3 are two or more inspection items V0 which guarantee that quality separately the whole analyzor 2. The various information containing that inspection result V5 is saved.
[0041] In addition, the validation data Dv managed by said validation program Pv and its program are easily incorporable into the configuration of the present analyzer 1 by recording on the record medium in which computer reading is possible. In this case, there is an advantage that the analyzer which has the validation function of this invention can be constituted very easily.

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[Translation done.]

* NOTICES *



1.This document has been translated by computer. So the translation may not reflect the original precisely.
2.**** shows the word which can not be translated.
3.In the drawings, any words are not translated.

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## DESCRIPTION OF DRAWINGS

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[Brief Description of the Drawings]
[Drawing 1] It is the schematic diagram showing the configuration of an example of an analyzer which has the validation function of this invention.
[Drawing 2] It is drawing showing the example of the various information displayed on the display of said analyzer.
[Drawing 3] It is drawing which indicates carrying out for the configuration of the conventional analyzer, and validation.
[Description of Notations]
1 [ -- A display, Dv / -- Various information, T / -- A chart and V0 / -- An inspection item and V5 -- Inspection result. ] -- An analyzer, 2 -- The analyzor, 3 -- An information processor, 3d

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[Translation done.]

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DRAWINGS

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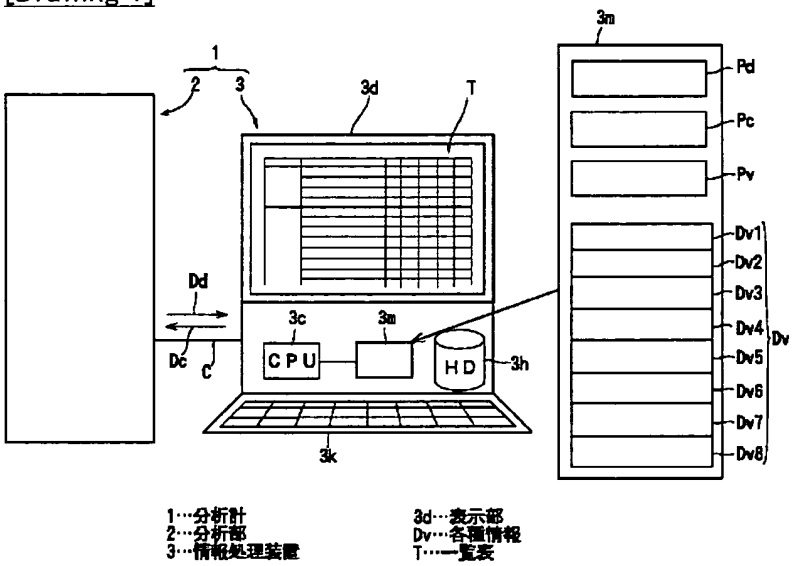
[Drawing 1]



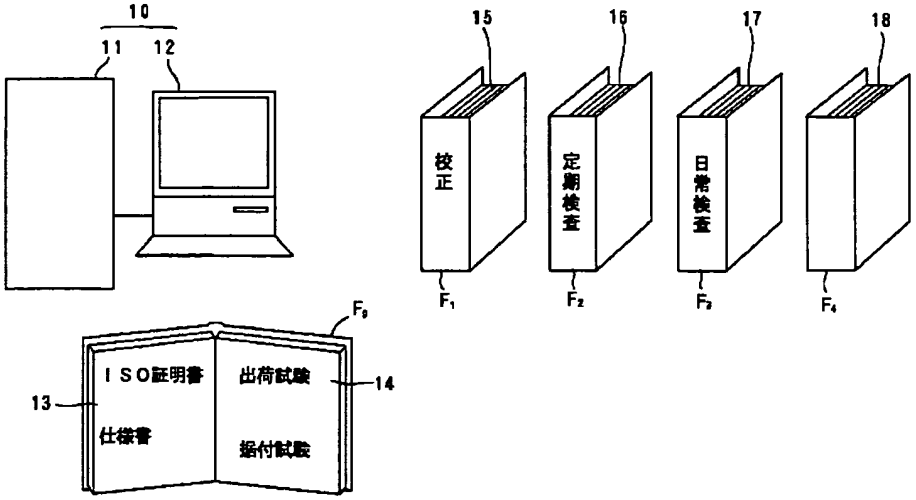

[Drawing 2]

| | 体系 | テスト項目 | テスト方法 ($V_1$) | 管理基準 ($V_2$) | 標準機器 標準試料 ($V_3$) | 帳票様式 ($V_4$) | 検査結果 ($V_5$) |
|---|---|---|---|---|---|---|---|
| Dv1 | 1. 要求仕様 (ユーザ) | 分析試料： | | | | | Au |
| | | 分析範囲： | Su | Su | Su | | Au |
| | | 併行精度： | Su | Su | Su | | Au |
| | | | | | | | Au |
| Dv2 | 2. 検定分析計型式 (メーカ) | 装置メーカ名： | | | | | |
| | | ＩＳＯ－９０００証明書 | | | | | Am |
| | | 型式名： 製造番号： | | | | | |
| | | 分析方式： | | | | | |
| | | 使用１次標準 | | | | | Am |
| | | トレーサビリティ体系 | | | | | Am |
| | | 標準試料併行精度 | Sm | Sm | Sm | Im | Am |
| | | 標準試料直線性 | Sm | Sm | Sm | Im | Am |
| | | 分析元素と分析範囲 | Sm | Sm | Sm | Im | Am |
| | | 感度 | Sm | Sm | Sm | Im | Am |
| | | 燃焼炉最大温度 | Sm | Sm | Sm | Im | Am |
| | | 電源電圧変動と周波数変動 | Sm | Sm | Sm | Im | Am |
| | | 環境温度変化と環境湿度変化 | Sm | Sm | Sm | Im | Am |
| | | 酸素流量変化と酸素圧力変化 | Sm | Sm | Sm | Im | Am |
| | | 干渉影響 | Sm | Sm | Sm | Im | Am |
| | | 振動 | Sm | Sm | Sm | Im | Am |
| | | CEマーク： EMC試験： | | | | | Am |
| | | ソフトウェアValidation宣言書； | | | | | |
| | | | | | | | |
| Dv3 | 3. 出荷試験 (メーカ) | 計測部校正（標準ガス併行精度；標準ガス直線性） | Sm | Sm | Sm | Im | Im |
| | | 標準試料併行精度 | Sm | Sm | Sm | Im | Im |
| | | 校正証明： | Sm | Sm | Sm | Im | Im |
| | | トレーサビリティ証明； | Sm | Sm | Sm | Im | Im |
| | | | | | | | |
| Dv4 | 4. 据付試験 (メーカ) | 据付けの適格性（仕様、ドキュメント、環境・ユーティリティ） | Sm | Sm | Sm | Im | Im |
| | | 操作性の適格性（動作、機能） | Sm | Sm | Sm | Im | Im |
| | | 性能確認（併行精度） | Sm | Sm | Sm | Im | Im |
| | | ソフトチェック（改算チェック:SUMコード、日付、ファイルサイズ、標準データチェック） | Sm | Sm | Sm | Im | Im |
| | | | | | | | |
| Dv5 | 5. 校 正 (メーカ/ユーザ) | 性能（併行精度、直線性；標準ガス、標準試料） | SuSm | SuSm | SuSm | OuIm | AuIm |
| | | ソフトチェック（改算チェック:SUMコード、日付、ファイルサイズ、標準データチェック） | SuSm | SuSm | SuSm | OuIm | AuIm |
| | | 検量性（検量線作成） | SuSm | SuSm | SuSm | OuIm | AuIm |
| | | | | | | | |
| Dv6 | 6. 定期検査 (ユーザ) | メンテナンス | Su | Su | Su | Ou | Au |
| | | 性能適格性（併行精度） | Su | Su | Su | Ou | Au |
| | | | | | | | |
| Dv7 | 7. 日常検査 (ユーザ) | メンテナンス | Su | Su | Su | Ou | Au |
| | | 検量性適格性（ＱＣ試料分析：併行精度、正確さ） | Su | Su | Su | Ou | Au |
| | | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Dv8 | 0. 分析法 (ユーザ) | 待ち時間： 秒<br>コンバレータレベル： %<br>コンバレータ判定待ち時間：秒<br>炉温度：<br>Step1： ～ ℃、 秒<br>Step2： ～ ℃、 秒<br>サンプル： gr.<br>助燃剤： 、 gr. | 特異性(抽出カーブ) | Su | Su | Su | Ou | Au |
| | | | 真度(対標準試料精度) | Su | Su | Su | Ou | Au |
| | | | 精度（併行、室内） | Su | Su | Su | Ou | Au |
| | | | 検出限界(3.3*SD) | Su | Su | Su | Ou | Au |
| | | | 定量限界(10*SD) | Su | Su | Su | Ou | Au |
| | | | 直線性(精度範囲内 対標準試料精度内) | Su | Su | Su | Ou | Au |
| | | | 範囲(直線性の範囲) | Su | Su | Su | Ou | Au |
| | | | 頑健性(試料量変化、炉温度変化) | Su | Su | Su | Ou | Au |

$V_0$…検査項目
$V_5$…検査結果

[Drawing 3]




[Translation done.]